REMARKS

By this Amendment, claims 24, 31, 35, 40, 47, 53, 54, 55, and 57 have been amended and claims 9, 10, 11, 19, 20, 21, 22, 44, 51 and 52 have been canceled. Accordingly, claims 3-7, 13-17, 24, 26-36, 38, 40, 41, 46, 47 and 53-57 are presently pending in the application. A version showing the changes made to claims 24, 31, 35, 40, 47, 53, 54, 55, and 57 is included as "Attachment A."

35 U.S.C. §101

In the prior Office Action, the Examiner rejected claims 40, 47, 53 and 57 under 35 U.S.C. §101 on grounds that such claims improperly defined a process. By this Amendment, claims 40, 47, 53 and 57 have been amended to more properly define the invention. Reconsideration of the rejections is respectfully requested.

35 U.S.C. §112

In the prior Office Action, claims 4, 6-7, 14-17, 24, 31, 34, 40, 46, 51, and 53-55 were rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, such claims were rejected because they used the terms "and/or" and "predetermined amount". Applicants respectfully submit that such terms are clearly not indefinite and that the rejections are improper and should be withdrawn.

Webster's Ninth New Collegiate Dictionary defines the term "and/or" as a conjunction that is "used as a function word to indicate that two words or expressions

are to be taken together or individually." The term "and/or" is well understood in the English language and is not indefinite. It indicates that either one or both of the words it is referencing may apply. Applicants note that according to the USPTO web site, 36,543 patents have issued in the U.S. since 1996 that contain claims that include the term "and/or" (search query: aclm/"and/or"). Clearly, claims containing the term "and/or" are not indefinite, and the rejection of such claims under §112 should be withdrawn.

Applicants respectfully submit that use of the terminology "predetermined amount" is also definite and proper. Applicants note that according to the USPTO web site, 7,810 patents have issued in the U.S. since 1996 that contain claims that include the terminology "predetermined amount" (search query: aclm/"predetermined amount"). In addition, Applicants note that use of the terminology "predetermined amount" has been determined in several cases to be appropriate and definite. See, e.g. Lundy Electronics & Systems, Inc. v. Optical Recognitions Systems, Inc., 178 U.S.P.Q. 525 (E.D. Va.1973).

By this Amendment, claims 53-55 have been amended in response to the Examiner's rejections. Specifically, the phraseology "having the composition and amino acid sequence" or "having the composition" has been replaced with the definite phraseology "having the amino acid sequence." Therefore, it is Applicants' view that claims 53-55, as amended, now meet the requirements of 35 U.S.C. §112. Reconsideration of the prior rejections is respectfully requested.

35 U.S.C. §103

Claims 3-7, 9-11, 13-17, 19-22, 24, 26-36, 40-41, 44, 46-47 and 51-57 were rejected under 35 U.S.C. §103(a) as being unpatentable over Janusz et al. Inasmuch as claims 9-11, 19-22, 44, 51 and 52 have been canceled by this Amendment, the prior rejection thereof under 35 U.S.C. §103(a) is moot. However, as to the remaining claims, applicants respectfully submit that the prior rejection is improper.

The cited Janusz et al. reference discusses various studies of Colostrinin on mice and suggests that Colostrinin may be therapeutic in treating autoimmune disorders in mice. The cited Janusz et al. reference also states that Colostrinin may also be useful as a tool in studying the mechanisms of the immune system. However, the cited Janusz et al. reference clearly does not teach, suggest, or disclose the use of Colostrinin in humans, and in particular does not suggest the use of Colostrinin to treat neurological disorders in humans.

All of the claims pending in the application claim the use of Colostrinin in treating neurological disorders and/or as a dietary supplement. As noted above, the cited Janusz et al. reference discusses the use of Colostrinin in the context of immune disorders in mice; not in the context of neurological disorders or as a dietary supplement as claimed. The cited Janusz et al. reference clearly does not suggest the desirability of the claimed invention, as there is no suggestion or motivation in such reference to use Colostrinin to treat neurological disorders. Applicants contend that there is no reasonable expectation of success that if a compound has immunological activity in mice, it will have a beneficial use in the treatment of neurological disorders or as a

dietary supplement in humans. The literature is replete with compounds that have activity in mice, but none in humans, and vice versa. Applicants respectfully submit that the pending claims are clearly not obvious in view of the cited reference under 35 U.S.C. §103.

Claims 31, 35, 54 and 55 include a limitation that the Colostrinin be in a form for oral administration to a patient. In the cited Janusz et al. reference, which discusses the immunological activity of Colostrinin in mice, Colostrinin was administered parenterally (i.e., other than by way of the intestines) as is typical in the treatment of problems having a viral etiology. There is clearly no teaching or suggestion that Colostrinin would be effective when administered orally, and it is therefore surprising that the oral administration of Colostrinin produces any therapeutic effect.

On April 2; 2002, applicants submitted an Information Disclosure Statement identifying Moller et al., U.S. Pat. No. 5,710,132, as prior art. Moller et al. discloses that bovine colostral milk can be used to improve liver function and prevent the sequelae of liver diseases such as portal encephalopathy. Applicants note that the present application is directed to the use of Colostrinin, which is a specific peptide-containing fraction of colostral milk, in the treatment of central nervous system disorders whereas Moller et al. teach the use of bovine colostral milk in the treatment of the liver to prevent the occurrence of diseases such as portal encephalopathy.

Claim 57 of the present application, which does claim the use of Colostrinin for use in preventing or inhibiting the development of chronic disorders of the central nervous system, specifies that the Colostrinin be in "isolated form" (as disclosed on

page 5, line 18 to page 6, line 8 of the specification). Moller et al. does not teach the use of Colostrinin in isolated form to prevent or inhibit the development of chronic disorders of the central nervous system.

CONCLUSION

In light of the foregoing, it is submitted that claims 3-7, 13-17, 24, 26-36, 38, 40, 41, 46, 47 and 53-57 are in condition for allowance, and a notice to that effect is therefore earnestly solicited.

Respectfully submitted,

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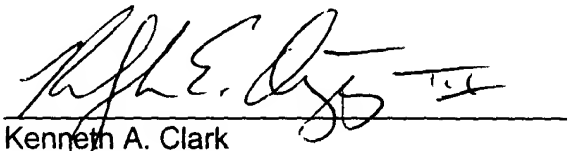

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ATTACHMENT A

(Version of Claims With Markings Showing Changes Made)

24. (TWICE AMENDED) A method of treating disorders of the central nervous system [and/or of the immune system,] comprising administering a predetermined amount of a composition [containing] comprising Colostrinin to a human patient for a predetermined period of time.

31. (TWICE AMENDED) A pharmaceutical composition for [humans] oral administration to a human patient comprising a preselected amount of Colostrinin in combination with a physiologically acceptable carrier.

35. (THRICE AMENDED) A composition according to claim 31[,] in the form of a tablet, lozenge[,] or gel[, patch or plaster].

40. (AMENDED) [The use of Colostrinin as a] A dietary supplement for babies, small children, adults who have been subjected to chemotherapy and/or adults who have suffered from cahexia, or weight loss due to chronic disease, comprising Colostrinin in isolated form.

47. (AMENDED) [The use of Colostrinin in the manufacture of a prophylactic medicament for humans, to prevent or inhibit the development of Alzheimer's

disease] A method of preventing or inhibiting the development of Alzheimer's disease comprising the administration of a prophylactic medicament comprising Colostrinin.

53. (TWICE AMENDED) [The use of] A medicament for treating chronic disorders of the central nervous system comprising a nonapeptide having the [composition and] amino acid sequence Val-Glu-Ser-Tyr-Val-Pro-Leu-Phe-Pro (SEQ ID NO:1) [in the manufacture of a medicament for treating chronic disorders of the central nervous system].

54. (TWICE AMENDED) A pharmaceutical composition for oral administration to a patient comprising a nonapeptide having the amino acid sequence [composition] Val-Glu-Ser-Tyr-Val-Pro-Leu-Phe-Pro (SEQ ID NO:1) in combination with a physiologically acceptable carrier.

55. (TWICE AMENDED) A method of making a pharmaceutical composition comprising combining a nonapeptide having the [composition and] amino acid sequence Val-Glu-Ser-Tyr-Val-Pro-Leu-Phe-Pro (SEQ ID NO:1) with a physiologically acceptable carrier to form a mixture, and [forming] altering said mixture [into] to create a form of said mixture [in which it can be administered] suitable for oral administration to a patient.

57. (AMENDED) [The use of colostrinin in the manufacture of a prophylactic medicament for humans, to prevent or inhibit] A prophylactic medicament for humans for use in preventing or inhibiting the development of chronic disorders of the central nervous system comprising Colostrinin in isolated form.